Biotribological study of large diameter ceramic-on-CRF-PEEK hip joint including fluid uptake, wear and frictional heating

Qian Qian Wang[1], Jun Jie Wu[1*], Anthony Unsworth[1], Adam Briscoe[2], Marcus Jarman-Smith[2], Conor Lowry[3], David Simpson[3], Simon Collins[3]

1. School of Engineering and Computing Sciences, Durham University, Durham DH1 3LE, United Kingdom

2. Invibio Limited, Lancashire FY5 4QD, United Kingdom

3. Corin Limited, Gloucestershire GL7 1YJ, United Kingdom

*Corresponding author: Dr Jun Jie Wu

School of Engineering and Computing Sciences

Durham University

South Road, Durham DH1 3LE, United Kingdom

Phone: +44 (0) 191 33 42440

e-mail: junjie.wu@durham.ac.uk

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Abstract

A novel material combination of a large diameter Biolox® Delta head and a pitch-based carbon fibre reinforced poly ether-ether-ketone (CFR-PEEK) MOTIS® cup has been studied. The acetabular cups were inclined at three angles and tested using Durham Hip Simulators. The different inclination angles used did not have a significant effect on the wear rates (ANOVA, p = 0.646). Averaged over all cups, the wear rates were calculated to be 0.551±0.115 $mm^3/10^6$ cycles and 0.493±0.107 $mm^3/10^6$ cycles taking account into two types of soak controls; loaded at room temperature and unloaded at 37°C respectively. Averaged across all femoral heads, the wear rate was 0.243±0.031 $mm^3/10^6$ cycles. The temperature change of the lubricant caused by the frictional heat was measured *in situ*. Friction factors measured using the Durham Friction Simulator were lower for the worn CFR-PEEK cups compared with unworn. This correlated with the decreased surface roughness. Even though relatively high friction was observed in these hemispherical hard-on-soft bearings, the wear rate is encouragingly low.

Keywords: Total hip replacement, Biolox® Delta, CFR-PEEK MOTIS® hemispherical cup, Wear, Friction, Hard-on-soft hip bearings

1. Introduction

Concerns over aseptic loosening and high levels of metal ions in metal on metal articulations, suggest that there is an increasing need for alternative material combinations for total hip prostheses [1-3]. The younger physically active patient demands a hip prosthesis with improved performance. Relatively large diameter bearing couples have been developed to improve joint stability and decrease the dislocation rates. They have been shown to offer better proprioception and provide a greater range of motion [4]. However, concerns have arisen over the potentially increased wear due to the longer sliding distance in larger bearings. A study by Clarke *et al*. found that large metal-on-metal bearings led to a greater systemic exposure of cobalt and chromium ions than bearings of small diameter [1]. Given recent concerns over the adverse effects of metal ion release, the development of alternative hip joint replacement materials has become increasingly important. This study is therefore concerned with a novel material combination of a Biolox® Delta ceramic head articulating against a hemispherical CFR-PEEK MOTIS® cup.

PEEK, a leading high-performance thermoplastic candidate for replacing metal implant components since the late 1990s, is being increasingly used for trauma, spinal and orthopaedic implants [5]. It is a biocompatible material with excellent mechanical properties suited to orthopaedic use. Carbon-fibre reinforced PEEK (CFR-PEEK) has been specifically developed to provide a light-weight, injection-mouldable alternative to traditional structural implant materials, meeting the mechanical requirements of joint arthroplasty. In an *in vitro* hip simulator study, Wang *et al*. reported that the carbon fibres strengthened the PEEK matrix and led to a reduction of wear rate of almost two orders of magnitude when compared with conventional UHMWPE [6]. Furthermore 30 wt% pitch-based CFR-PEEK showed the best wear-resistant ability among all cases in their study. The enhanced wear performance of CFR-PEEK was reported by Scholes *et al*. [7, 8]. In contrast to previous investigations that used alumina or zirconia as the hard counterparts, the latest-generation of zirconia-toughened-alumina (ZTA), Biolox® Delta (CeramTec AG, Plochingen, Germany) was used in this study. Alumina is an attractive ceramic for orthopaedic implants due to its good tribological characteristics chemical and physical stability. However its poor toughness has led to some occurrences of material fracture occurring in hip prostheses [9]. In contrast zirconia shows excellent mechanical properties in terms of high strength and fracture toughness, but has intrinsic hydrothermal instability which together with the phase change of the material may roughen the bearing surface and consequently increase polyethylene wear [10]. ZTA is a composite with fine zirconia particles uniformly incorporated into the alumina matrix by means of the stress induced transformation process, and combines the characteristics of both ceramics with low wear and high toughness. The platelet-like crystals and the phase change of zirconia particles under mechanical stress can effectively stop crack propagation [11]. The *in vitro* study by Al-Hajjar *et al*. reported lower wear rates of full Biolox® Delta ceramic bearings compared with those of alumina-on-alumina ones [12]. To date the performance of Biolox® Delta in ceramic-on-polyethylene bearings has not been well addressed in the literature.

In this study the novel material combination of a Biolox® Delta ZTA head and a CFR-PEEK MOTIS® cup was evaluated for their biotribological performance *in vitro*. The bearing couples were designed with a large diameter of 40 mm. Sensitivity to inclination angles was assessed and temperature rise due to frictional heat generation in the bearings was measured *in situ*. Friction factors were measured on both worn and unworn joints.

2. Materials and Methods

The novel hip prosthesis comprised a Biolox® Delta ZTA head, CFR-PEEK MOTIS® liner and a titanium (Ti6Al4V) acetabular shell (Figure 1). The composite liners machined from injection moulded near net shapes were made from 30 wt% pitch-based carbon fibre within a PEEK matrix (provided by Invibio Limited, UK). Biolox® Delta heads (provided by Corin Limited, UK) were chosen in this study as the hard counterparts to match with CFR-PEEK cups. The bearing components were designed to have a diameter of 40mm. Using a coordinate measuring machine, the diametral clearance was determined to be 327.8±18.9 μm (mean ± standard deviation) averaged among five bearing couples tested.

The wear test was conducted using the Durham Hip Wear Simulator. The joint components were mounted anatomically to produce inclination angles corresponding to 60° (*n*=2), 55° (*n*=2) and 45° (*n*=1) *in vivo*, where *n* was the number of joints. To mimic the physiological conditions in the walking gait, the active wear stations applied a simultaneous flexion/extension (F/E) motion to the femoral component and internal/external (I/E) motion to the acetabular component. The crank arrangement drove the components to oscillate with an approximate sinusoidal motion through -15° to 30° in F/E plane and -5° to 5° in I/E plane. Both of the motions oscillated at 1Hz and with a phase difference of 90^o between them to simulate the correct wear vector over the bearing surfaces. The simulator was driven pneumatically to provide a square wave loading pattern with minimum and maximum loads of ~300 N to ~2200 N respectively [13].

To monitor the fluid absorption of the joint components throughout the test, extra hip joints were prepared. One joint employed a 'load soak' control fixed in the creep station which underwent dynamic loading only and was at room temperature. The other joint was placed in the same solution and kept isothermal at 37°C and was termed the 'soak' control. Before the wear test started, all CFR-PEEK cups had been soaked for 50 days in order to achieve saturation.

The articulating surfaces were lubricated by 25% (v/v) diluted bovine serum (Harlan Laboratories Limited, UK), which gave a protein content of approximately 17.5 g/L [14]. The anti-bacterial agent, 0.2% sodium azide (NaN_3), was added to inhibit bacterial growth, and 20mM EDTA was used to prevent calcium deposition. The wear test was conducted at room temperature up to 7.5×10^6 cycles, stopping approximately every 0.5×10^6 cycles. At every 0.5×10^6 cycles, acetabular and femoral components were cleaned according to the cleaning/drying protocol defined in ISO 14242-2:2000 and prepared for gravimetric measurement and surface roughness analysis. The masses of the heads and cups were measured gravimetrically using a Mettler AE 200 balance with an accuracy of 0.01 mg [15]. Finally, before resuming the next 0.5×10^6 cycles, the lubricant was replaced with fresh lubricant.

Temperature increases in the lubricant of the active wear stations were observed during the tests. To record the temperature changes quantitatively, a PC-based logging device (manufactured by PICO Technology) was used to connect with a K-type thermocouple. In each station, the thermocouple was inserted through a 1 mm diameter hole in the cup holder. The distance between the tip of the thermocouple and the articulating bearings was *ca* 8 mm. We also measured the environmental room temperature in the hip simulator laboratory to provide the baseline. The temperatures were recorded at intervals of 500 seconds. The real-time measurement lasted for the entire 0.5×10^6 cycles. In order to track the temperature changes after the simulator stopped, the data logging continued for 10 hours at intervals of 20 seconds.

Friction measurements were carried out using the Durham Hip Friction Simulator. The simulator comprised a low-friction carriage, in which the acetabular cup was fixed, and an upper rotating frame, in which the femoral head was fixed. The prosthesis was placed inversely relative to the position *in vivo*. To measure the friction accurately, the axes of rotations of the joint components in the upper frame and the carriage were aligned precisely. A simple harmonic oscillatory motion with an amplitude of 24° was applied to the femoral head in the F/E plane. The period was 1.2 s. The simulator was driven by a servo-hydraulic mechanism and controlled by a computer via a microprocessor. The dynamic load applied in one cycle varied in the range from 100N to 2000N. The rotation of the acetabular cup was resisted by a Kistler piezoelectric transducer to measure the frictional torque produced. It was converted to the friction factor f based on the formula

$$f = \frac{T}{RL}$$

where T is the frictional torque between the bearing couples, R is the radius of the femoral head and L is the load applied [16]. The measurement was made in both normal and inverse directions to eliminate residual errors. The simulator was programmed to run for 41 cycles to obtain stability. The data were selected at the peak load and high velocity phase of the last cycle.

Two pairs of worn joints with the initial diametral clearance of about 320 μm were used in the friction testing. The worn acetabular cups fixed at the inclination angles of 45° and 55° during the wear test were kept in the same positions during the friction testing. This ensured that the friction measurements were made in the worn areas. Furthermore, a new unworn joint with the same size and similar clearance was also tested at both 45° and 55°. The articulating surfaces were lubricated by both water based carboxy methyl cellulose (CMC) fluids and 25% diluted bovine serum based CMC fluids respectively. They were prepared to have the viscosities of 0.001, 0.003, 0.01, 0.03 and 0.1 Pa·s, which were measured on a Ferranti-Shirley cone-on-plate viscometer at a shear rate of 3000 s^{-1} at room temperature. For every lubricant, friction tests were performed three times on each joint, either worn or unworn. Stribeck analysis was used to give an indication of the lubrication regime, in which friction factor was plotted against the Sommerfeld number z defined as

$$z = \frac{\mu R u}{L}$$

Here μ is the viscosity of the lubricant and u is the entraining velocity of the bearing surfaces [16].

3 Results

3. 1 Mass Changes of Soak and Load Soak Controls to Monitor Fluid Uptake

Controls were employed for femoral and acetabular components to take account of the fluid absorption throughout the wear test. A negative value means mass loss whereas a positive value indicates mass gain. The same definitions were applied for the wear plots below. As expected, the load soak and soak controls of ceramic heads showed the same varying trends and magnitudes as shown in Figure 2a. There is a puzzling mass gain between 3.0MC and 3.5MC with the soak head control and the load soak head control showing nearly the same amount of gain In the corresponding measurements, a relatively large mass gain was noticed to occur for soak cup control and load soak cup control as well. The profiles of total mass changes are illustrated in Figure 2b. We believe that these mass gains could have been introduced by the external factors in the weighing procedure, e.g. the changes of environmental temperatures and humidity (which did change more at the point in question than any other point), or possibly balance error. Most importantly the gradient of the mass loss of the heads before 2.0 Mc and after 3.5 Mc are the same. Owing to this consistency we believe the wear rates to be accurate. Furthermore we extended the run from 5 Mc to 7.5 Mc in order to have confidence in the wear rate.

Initially the CFR-PEEK acetabular cups showed increasing mass trends with time as shown in Figure 2c. As expected, the load soak CFR-PEEK cup gained mass gradually at room temperature. Also the soak control cup, soaked at 37°C, gained mass and this is attributed mainly to the elevated temperature of 37°C. This fluid uptake was larger in comparison to the load soak control cup, fixed in the creep station which remained at room temperature throughout the test period. Later the rate of fluid uptake by both controls were similar. Whilst post-processing the wear data, the mass changes of the load soak control were chosen for the worn ceramic heads; both load soak and soak controls were used for the worn CFR-PEEK cups.

3. 2 Wear Measurements

Approximately every 0.5×10^6 cycles the worn joint components were measured gravimetrically to determine the mass changes. After adjustments using the controls, the net mass changes were converted into volumetric changes using densities of 4889 kg/m^3 for ceramic heads and 1350 kg/m^3 for CFR-PEEK cups. In Figure 3a, wear is displayed for each femoral head. The comparison between different inclination angles is made in Figure 3b. A running-in stage was not observed for the Biolox® Delta heads while articulating against CFR-PEEK cups. The effect of inclination angles on wear was apparently small. Averaged across all femoral heads, the wear rate was 0.243±0.031 mm^3/10^6 cycles (mean ± standard deviation).

Wear plots for acetabular CFR-PEEK cups are presented in Figure 4. Adjusted by the load soak control, cups showed mass gains initially during the first 3×10^6 cycles. After this initial gain, consistent material loss took place as displayed in Figure 4a. As shown in Figure 4b, the cups (when adjusted using the soak control data) showed material loss starting after around 1×10^6 cycles. Only the data in the period of consistent material loss was used for the wear rate calculation. The comparisons made in Figure 5 indicated that there were comparable wear rates between the two configurations. Statistically, no significant differences in wear rates were observed for different inclination angles (ANOVA, $p = 0.646$). Averaged among all acetabular cups at three angles, the wear rates were 0.551 ± 0.115 $mm^3/10^6$ cycles taking account of the load soak control and 0.493 ± 0.107 $mm^3/10^6$ cycles taking account of the soak control. The tests suggest that initially the amount of liquid taken up by the samples in the active stations was slightly higher than that taken in by the soak control at 37°C and distinctly higher than that by the loaded soak control at room temperature. As the active stations were found to operate at around 44°C, the mass gains are probably due to the relatively higher temperatures of the active station leading to higher absorption of fluid.

3. 2 Structural Characterisation

The bearing surfaces of both hard and soft counterparts were examined using a non-contacting profilometer (Zygo) when the wear tests were stopped at 2.5×10^6, 5.0×10^6 and 7.5×10^6 cycles. To characterise the changes of the surface property, surface roughness in terms of Root Mean Square Roughness (*rms*) was measured and is presented in Figure 6. The scales are micrometers for the CFR-PEEK MOTIS®cups (Figure 6a) and nanometers for Biolox® Delta heads (Figure 6b). The ceramic heads became relatively rougher and the cups relatively smoother and large changes took place within the first 2.5×10^6 cycles for both heads and cups. Averaged among the data obtained at the three stages, the worn cups and heads had roughnesses of 0.78 μm and 5.9 nm respectively in contrast to an average *rms* of 2.3 μm for the unworn cups and an average *rms* of 3.7 nm for the unworn heads. An extensive examination of the ceramic heads was conducted at the final stage to determine the worn areas. It was found that the worn area mainly covered the surface extending from the pole to the polar angle of 30°.

Zygo images (Figure 7) show the typical features observed on the worn areas of CFR-PEEK cups. The mottled texture, originally widespread on the unworn surface was mainly removed, however some remained visible. Carbon fibre protrusion on the surface was clearly seen. Where it was evident that fibres had broken into segments, a dashed circle was used to highlight this. Some fibres were removed from the cup as debris. The broken fibres were typically about 1 μm deep and 10 μm long. These broken fibres were assumed to be mainly partial fibre pull-out since original fibres are of *approx.* 8μm in diameter and 20 μm long.

The surface structural features of the ceramic heads were examined using Atomic Force Microscopy (AFM) as shown in Figure 8. Figure 8a gives typical surface features of the unworn Biolox® Delta heads showing original polishing marks. Figure 8b gives typical surface features of the wear zone on the worn Biolox® Delta heads showing the removal of polishing marks and some partial ceramic grain pull-out.

3. 3 Friction Measurements

Figures 9 and 10 compare unworn joints with worn joints tested at 45° and 55° inclination angles. Figures 9b and 10b showed that the inclination angle had no effect on friction factor for the unworn joints. However, for the worn joints, slightly increased friction factors were observed in the worn joints tested at higher inclination angle, i.e. 55°, as shown in Figures 9a and 10a (ANOVA, $p < 0.05$). The decreasing trends shown in Figure 10 suggested that both worn and unworn joints operated in the mixed lubrication regime. At 45° the worn bearings produced lower friction factors than the unworn ones. The bovine serum based CMC fluid with viscosity of 0.01 Pa·s was believed to be very close the physiological synovial fluid. Based on the definition of the friction factor, the torque was estimated for the peak load of 2000 N. The values were 7.58±0.22 N·m for the worn joint inclined at 45°, 9.46±0.67 N·m for the worn joint at 55° and 9.59±0.12 N·m for an unworn joint inclined at 45°. For each couple the data were averaged among three tests.

3. 4 *in situ* Temperature Measurements

Figure 11a and 11b illustrate the temperature changes throughout the wear testing carried out at two different periods of time. The *x*-axis is the time in hours (43200 cycles at 1 Hz is equivalent to 12 hours). On each occasion five thermocouples were placed in the active stations, one in the creep station and one exposed in the air. In the first time period, the thermocouple in Station 1 failed at 334,279 cycles after the wear test started whilst the thermocouple in Station 3 failed at 41 000 cycles. All the other thermocouples ran properly throughout the 0.5Mc test. In the second time period no thermocouples failed. In the first time period the temperature rise was the highest for the joint (Cup 4 and Head 4) inclined at 55 degree, and the lowest for the joint (Cup 5 and Head 5) inclined at 45 degree. Station 4 was the one where the head had a 30% greater wear rate than the rest. In the second test, the maximum temperature rise occurred for the joints inclined at 55 degree generally throughout the wear test. But occasionally one joint inclined at 60 degree showed the higher temperature difference between it and ambient temperature.

As expected, similar trends were found between the profiles of room temperature and the load soak station, which had lower magnitudes and temporally lagged behind. Once the simulator stopped, the temperature reduced to the room temperature within the following 10 hours.

4 Discussion

Fluid absorption is common for CFR-PEEK. At the beginning of the test, continuous mass gains for CFR-PEEK cups in the active wear stations took place, even though they had been pre-soaked for 50 days before the test. This phenomenon was documented previously in the study of Scholes *et al*. [8]. From the weight data, CFR-PEEK demonstrated strong fluid absorption ability. Soaking temperature clearly plays a major role due to temperature influence upon diffusion. The soak control was held at 37°C and more fluid absorption was observed at 37°C than that at room temperature.

Consequently two wear rates with comparable magnitudes for each worn cup were obtained when adjusted by load soak control and soak control respectively. Although the load soak control in the creep station undertook the same dynamic loading as that of the active station (at room temperature), the soak control took place at 37°C (as body temperature had been chosen to be the reference point), which is closer to the temperatures in the active stations. These operated around 44°C due to the heat which arose from the friction of the prostheses. Ideally one would determine the average temperature of the active stations and operate both controls at this temperature. This has not been the practice to date. Indeed we believe this paper is the first to report in detail on the use of load soak and soak controls.

Inclination angles of hip prostheses *in vivo* are of clinical concern [3, 17], however *in vitro* testing has reported no significant effect of angle of inclination upon the wear rate for ceramic-on-ceramic couples [18]. Inclining the joints at high angles has been shown to expose the femoral and acetabular components to the risk of rim loading, especially with the presence of micro-separation. This has been suggested as a potential catalyst for an increase in wear [12]. Hart *et al*. considered that cups inclined at angles greater than 45° are associated with increased wear rates for metal on polyethylene hip replacements [17]. In addition, metal-on-metal couples showed higher levels of blood cobalt and chromium for replacements inclined at angles greater than 50°. In the current study, the effect of increasing inclination angles does not seem to have a significant effect upon wear but the degree of significance we can attach to this is low as there were only two samples in the 55 and 65 degree groups and one in the 45 degree group. In the configuration of ceramic-on-polymer bearing couples, the comparison was made between different material combinations in Figure 12. In contrast to the conventional UHMWPE cups with wear rates of 30-50 $mm^3/10^6$ cycles [19, 20], the CFR-PEEK MOTIS® cups in this study produced the magnitude approximately 100 times smaller. Current understanding is that Biolox® Delta ceramic has advantages in fracture toughness and stability in contrast to alumina and zirconia as alternative hard counterparts. Biolox® Delta has been investigated for full ceramic couples and proved to have an excellent wear performance [12]. In the design of metal-on-ceramic hip joints, zirconia toughened alumina showed the lower wear rate than alumina even in the severe wear conditions [21, 22]. This study was the first to address its use in combination with CFR-PEEK hemispherical cups and the wear rate is still encouragingly low.

In the literature, frictional heating has been mostly reported for hard-on-soft combinations. Some degree of temperature increases was addressed in *in vivo* studies for metal-on-metal, metal-on-polyethylene and ceramic-on-polyethylene implants [23, 24]. The increase in temperature is linked to the frictional energy from the articulating couples. The higher temperature, relative to the environment, raises concerns over potential thermal damage in the surrounding soft and hard tissues. Therefore, the relatively higher friction observed for CFR-PEEK joints compared with other bearing couples such as ceramic-on-ceramic is still a concern. The friction test in this study indicated that the combination of Biolox® Delta heads and CFR-PEEK MOTIS® cups operated in the mixed lubrication regime. The friction factors measured are in the range of 0.1 to 0.35. The surface roughness of the CFR-PEEK cup is believed to play an important role in enhancing the frictional performance of the ceramic-on-CFR-PEEK bearing couple. The comparison showed lower friction factors for the worn couples than the unworn. This correlates with the topography analyses which showed a decrease in surface roughness for worn CFR-PEEK cups.

5 Conclusions

The material combination of 40mm diameter Biolox® Delta heads and CFR-PEEK hemispherical cups was investigated in this study. Lower wear rates for ceramic-on-CFR-PEEK acetabular cups were found compared with those that are part of other ceramic-on-polymer or metal-on-polymer couples. There is no indication that an increase in inclination angle has a significant effect upon wear for the material combination used in this study. The friction test indicated that the bearing couples operated in a mixed lubrication regime. Lower friction factors were observed for worn couples due to their smoother surface. The frictional heat produced between bearing couples did result in rising temperatures of the lubricant during wear testing. A further study aiming to reduce the surface roughness of CFR-PEEK cups is planned in order to improve the frictional characteristics.

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Figure Legends

Figure 1 Photograph of the trinity hip joint: Biolox® Delta ZTA head, CFR-PEEK MOTIS liner and titanium shell

Figure 2 Total mass changes of the load soak and soak controls of ceramic heads (a); total mass changes of all heads including those in active stations (b); and total mass changes of load soak and soak controls of CFR-PEEK cups (c)

Figure 3 (a) Total volumetric changes of ceramic heads; (b) Wear rates at inclination angles of 60°, 55° and 45°

Figure 4 Total volumetric changes of CFR-PEEK cups: (a) adjusted by the load soak control; (b) adjusted by the soak control

Figure 5 Wear rates of CFR-PEEK cups for three inclination angles taking account of the load soak and soak controls respectively

Figure 6 Surface roughness for worn and unworn components at three testing stages – *rms*: (a) CFR-PEEK cups; (b) Biolox® Delta heads

Figure 7 Zygo images taken on worn CFR-PEEK cups to show the broken carbon fibre (circled by dashed line) and pull-out in the line profile

Figure 8 AFM images taken at Biolox® Delta heads: (a) unworn head; (b) worn head

Figure 9 Stribeck plots for lubricant of water based CMC fluids: (a) worn bearings inclined at 45° and 55°; (b) unworn bearings inclined at 45° and 55°

Figure 10 Stribeck plots for lubricant of bovine serum based CMC fluids: (a) worn bearings inclined at 45° and 55°; (b) unworn bearings inclined at 45° and 55°

Figure 11 Real-time temperature changes in active wear stations, creep station and simulator room: (a) 1st time period; (b) 2nd time period

Figure 12 Comparison with wear rates of polymer components as articulating against ceramic heads in the literature [6, 8, 9, 20]

Figure 1

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Figure 2a

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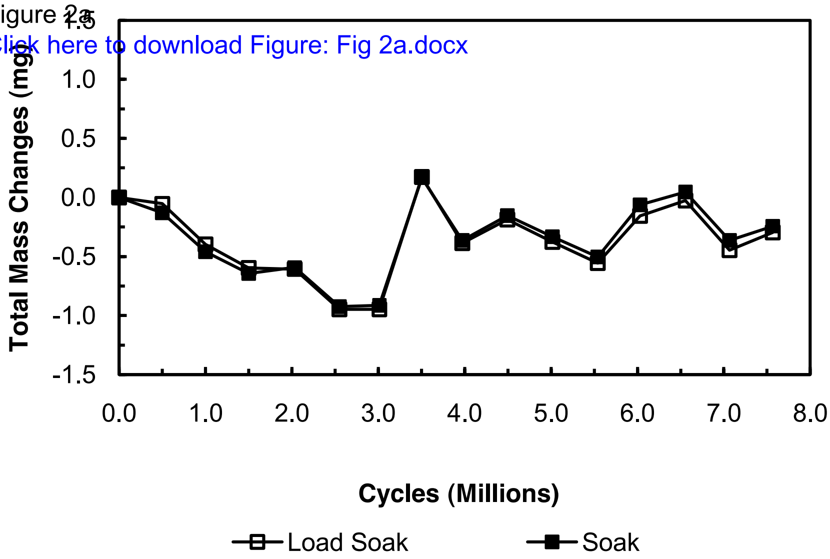

Figure 2b

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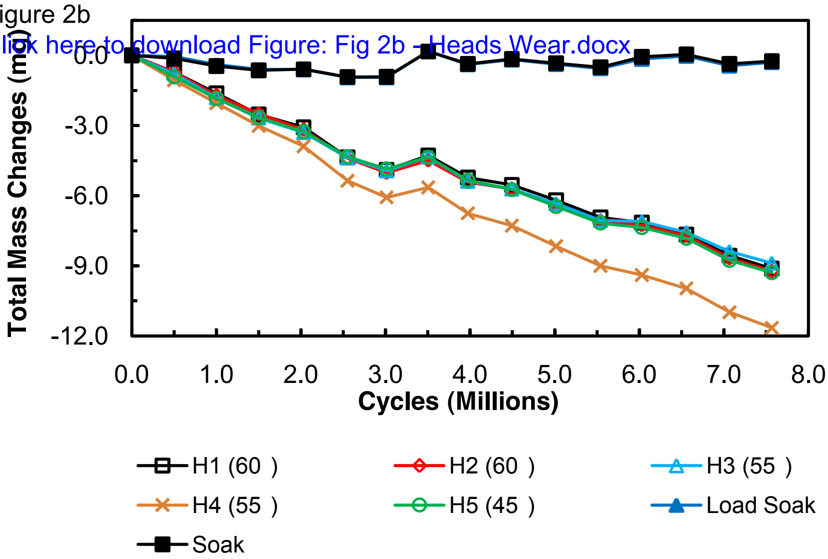

Figure 2c

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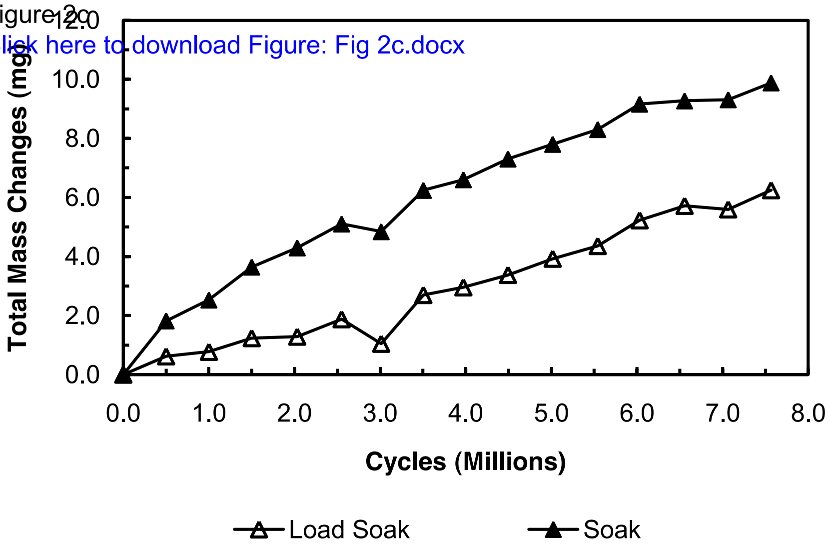

Figure 3a

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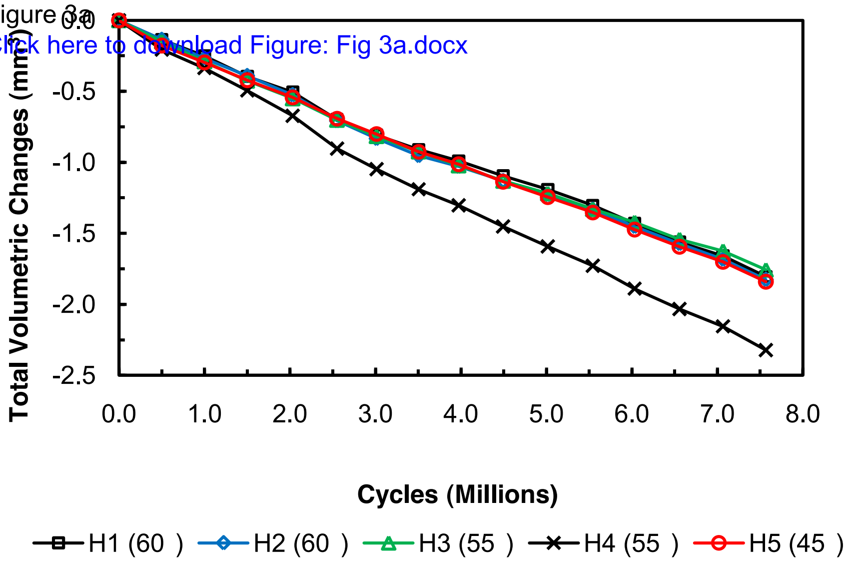

Figure 3b

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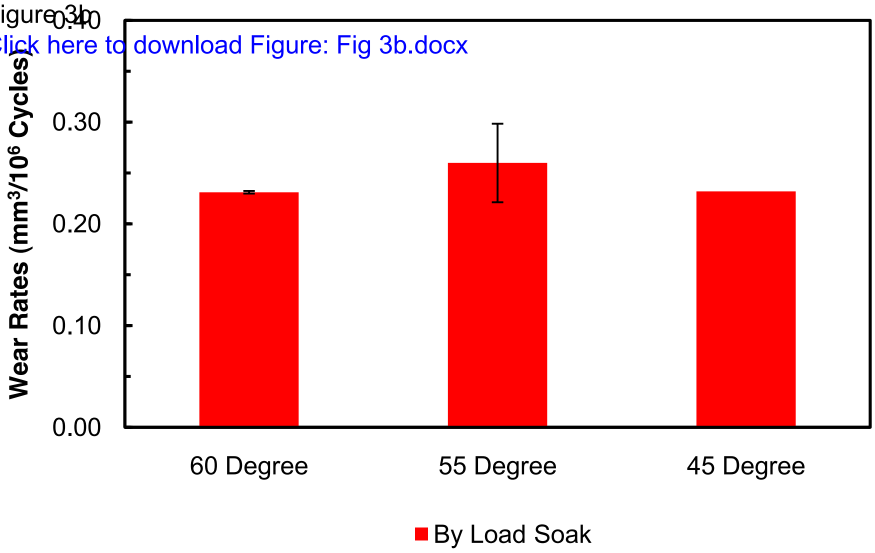
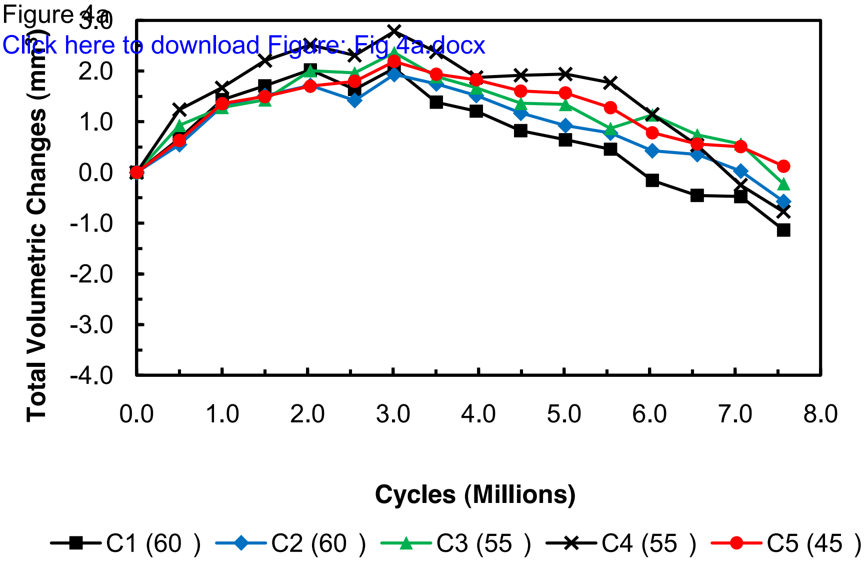


Figure 4a



Total Volumetric Changes (mm³)
3.0
2.0
1.0
0.0
-1.0
-2.0
-3.0
-4.0
0.0
1.0
2.0
3.0
4.0
5.0
6.0
7.0
8.0
Cycles (Millions)
C1 (60)
C2 (60)
C3 (55)
C4 (55)
C5 (45)

Figure 4b
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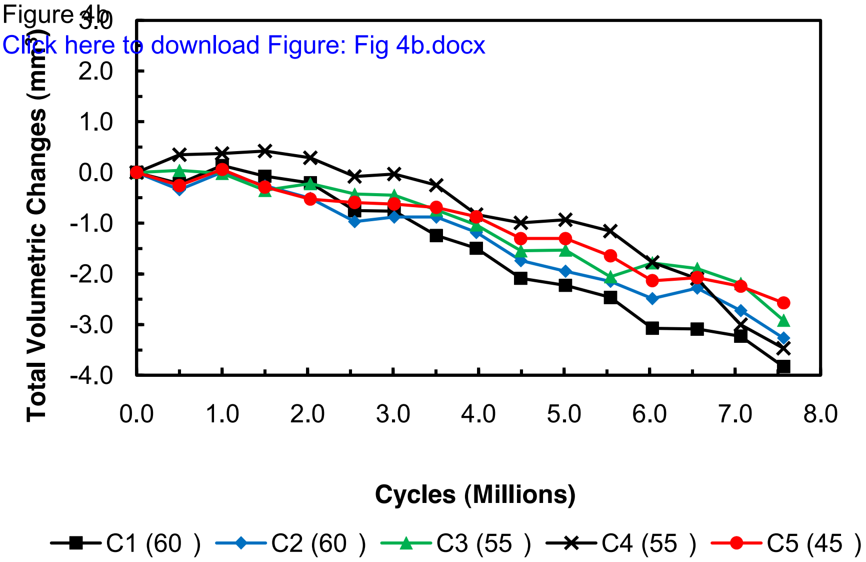

Figure 5

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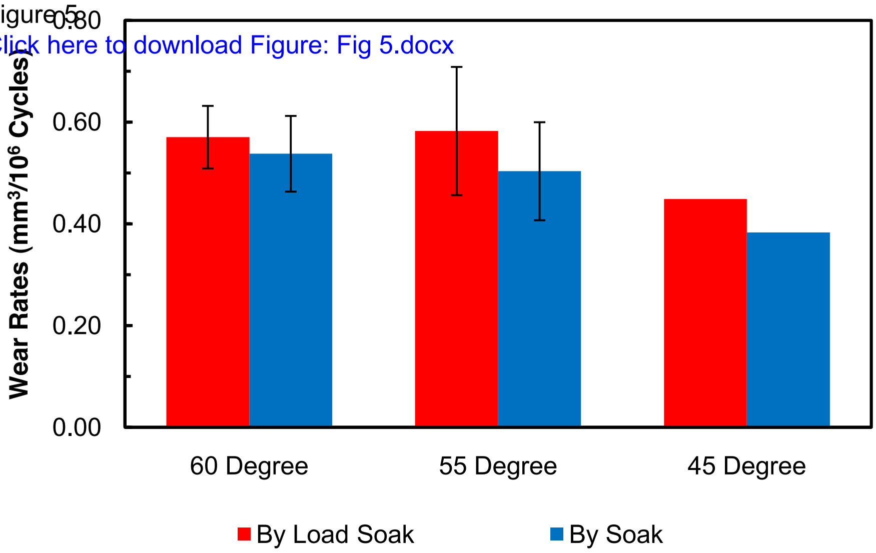

Figure 6a

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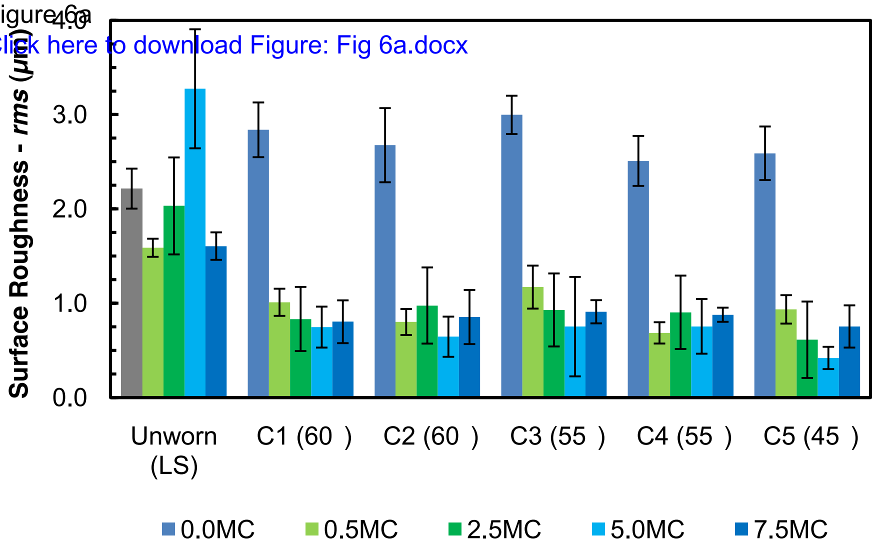

Figure 6b
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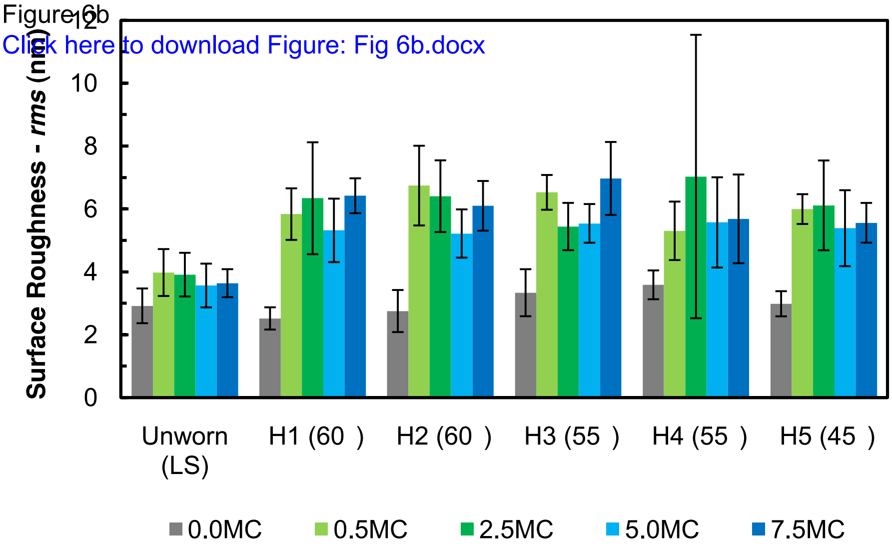

Figure 7
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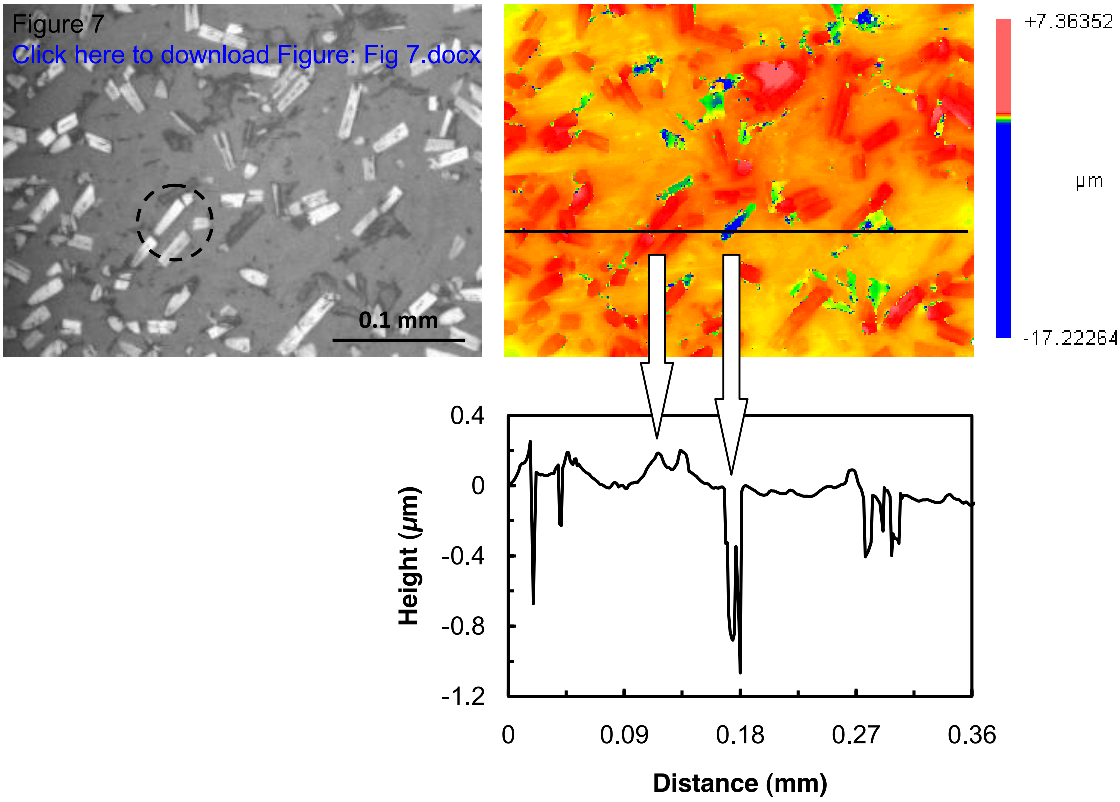

Figure 8a

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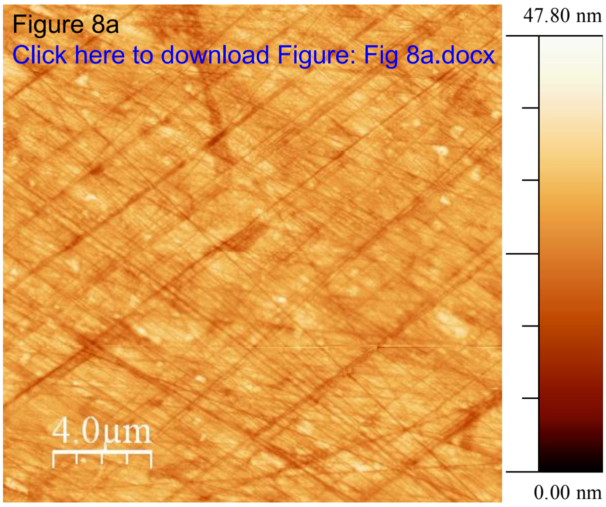

Figure 8b
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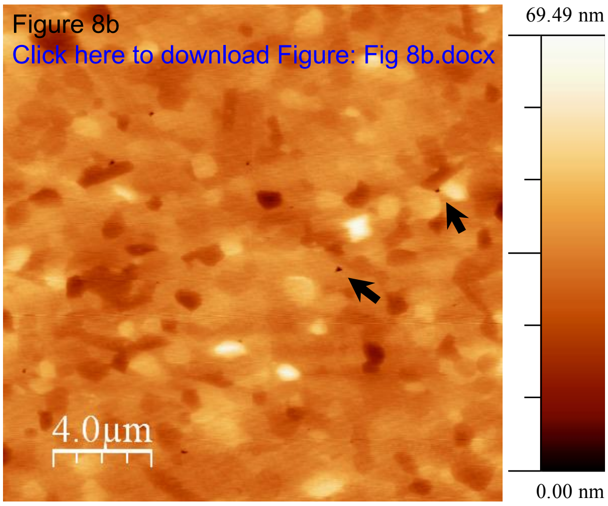

Figure 9a

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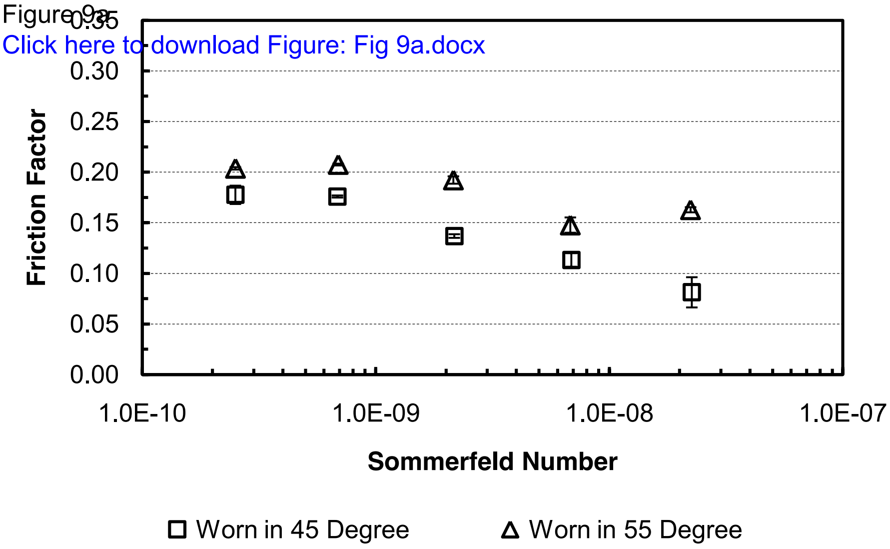

Figure 9b

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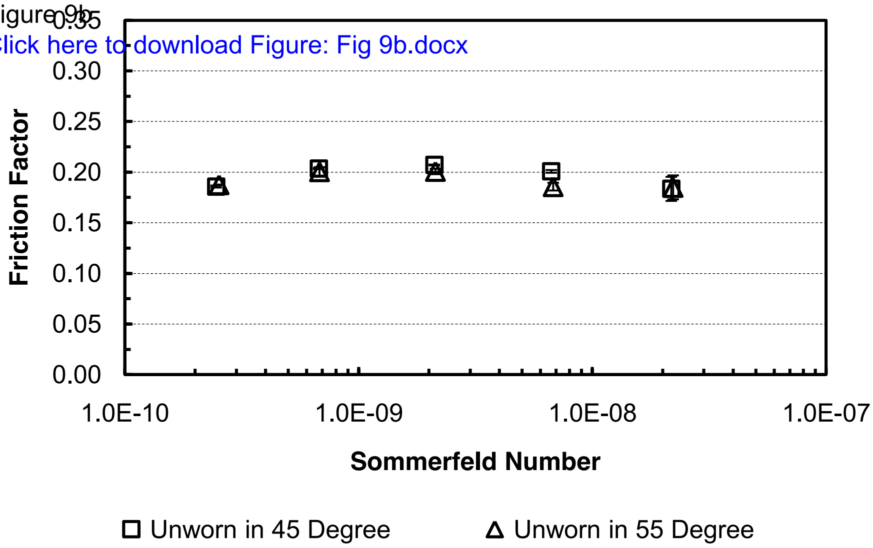

Figure 10a
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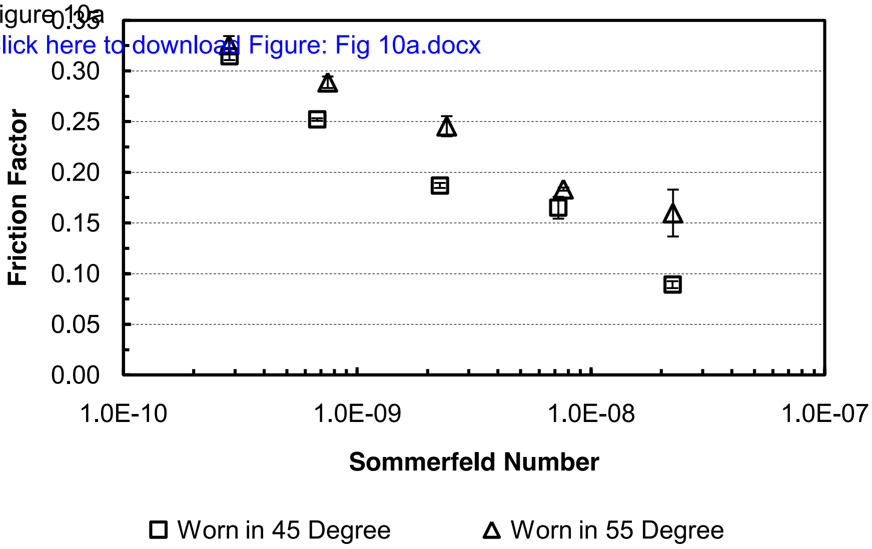

Figure 10b
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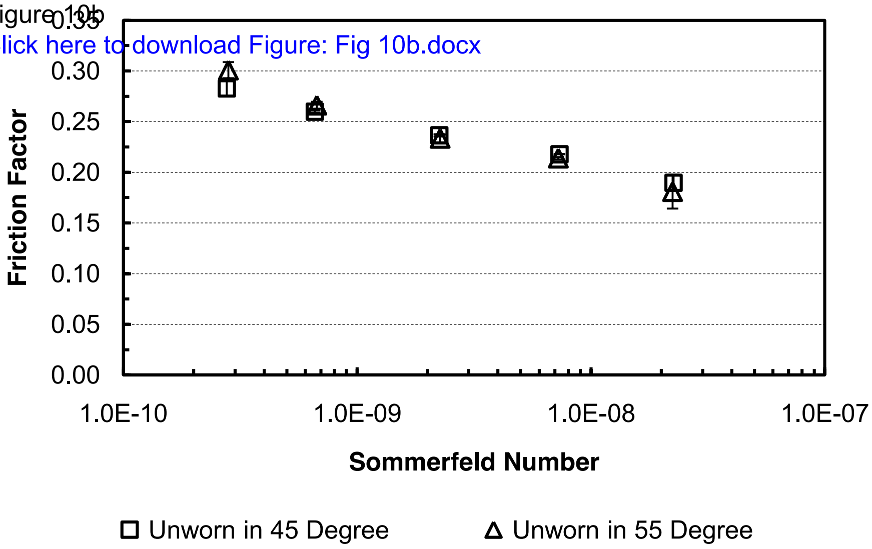

Figure 11a

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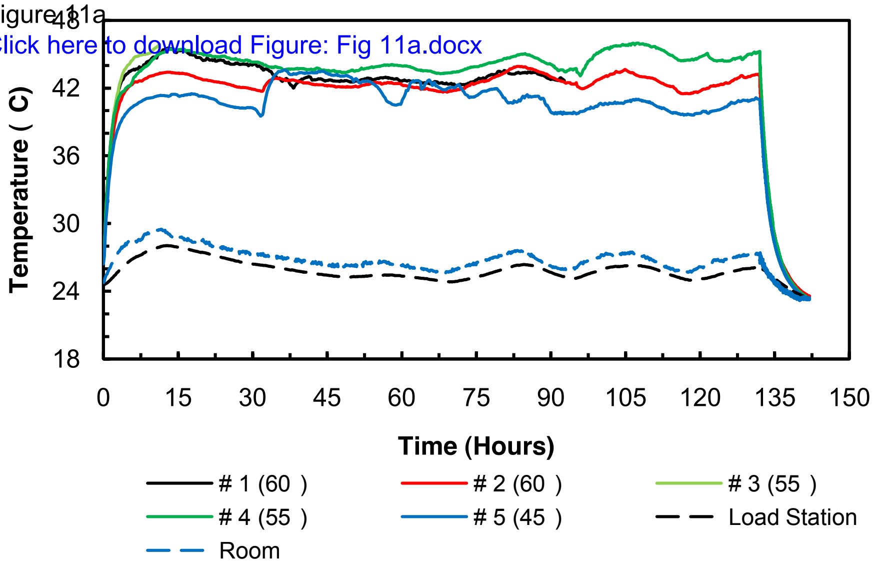

Figure 11b
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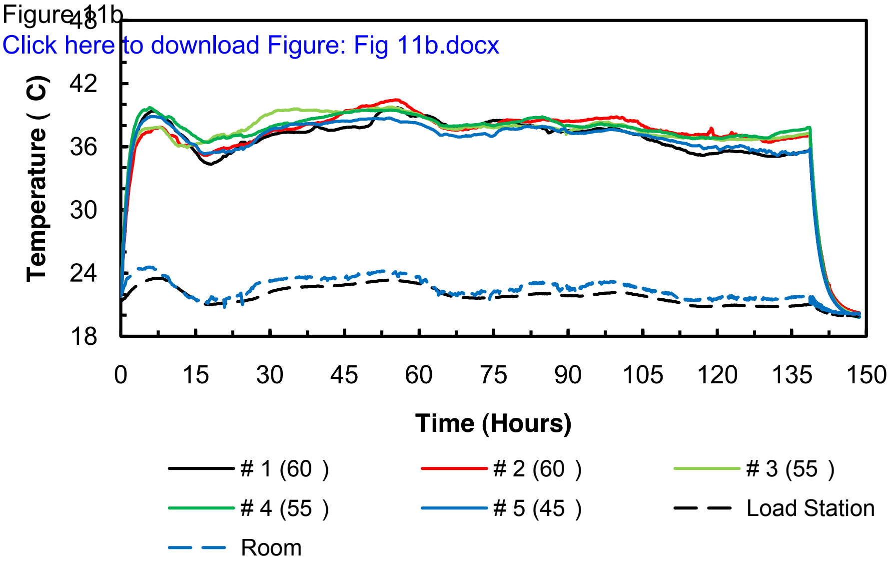

Figure 12

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